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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,924	01/17/2006	Roberto Crea	CREA-001US	2319
51951 7590 04/04/2008 THE LUTHER LAW FIRM 12198 E. COLUMBINE DR. SCOTTSDALE, AZ 85259				
EXAMINER FLOOD, MICHELE C				
ART UNIT 1655		PAPER NUMBER		
MAIL DATE 04/04/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,924

Applicant(s)

CREA, ROBERTO

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, drawn to a method of treating early diabetic neuropathy comprising administering a composition comprising an aqueous extract of olives.

Group II, claims 5-8, drawn to a method of treating patients with C-fiber neuropathy comprising an aqueous extract of olives.

Group III, claims 9-12, drawn to a method of treating patients with large fiber and C-fiber neuropathy comprising administering an aqueous extract of olives.

Group IV, claims 13-14, drawn to a method of treating patients with large and C-fiber neuropathy comprising administering an extract of olive leaves.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The four different groups are directed to four different methods of treatment. For instance, the invention of Group I is directed to a method of treating early diabetic neuropathy comprising the administration of an aqueous extract of olives; whereas the invention of Group II is directed to a method of treating patients with C-fiber neuropathy comprising the administration of an aqueous extract of olives; whereas the invention of Group III is directed to a method of treating patients with large fiber and C-fiber neuropathy comprising the administration of an aqueous extract of olives; and, whereas the invention of Group IV is directed to a method of treating patients with large fiber and C-fiber neuropathy comprising the administration of an extract of olive leaves. Moreover, most early diabetic subjects demonstrate a disorder of small somatic sensory nerves, *i.e.*, C-fiber neuropathy, which tends to be generalized to upper and lower limbs in contrast to

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large fiber diseases that originate in the lower limbs. While early diabetic neuropathy in patients present small-fiber dysfunction, an association between impaired glucose tolerance and neuropathy (especially painful neuropathy) must be established to determine that diabetes is the nature of the disorder, since heavy metal poisoning, amyloid, vasculitis, autoimmune disease, collagen vascular disease, chemotherapeutic drugs, Chagas' disease and familial disease causes are also considered as C-fiber neuropathies or at least the cause of the disease condition. In other words, C-fiber neuropathy is not limited to early diabetic neuropathy; large fiber neuropathy does not present in early diabetic neuropathy. However, both C-fiber and large fiber neuropathy is present in Wilson's disease, as well as other disease conditions. The marked differences in the altered activities of various forms of painful neuropathies caused by highly diverse insults to the peripheral nervous system generally require different methods of treatment since different mechanisms are involved in the pathology of the disease condition. While each of the methods of Groups I-III require the administration of an aqueous extract of olives to three different patient populations, the method of Group IV is directed to the administration of an extract of olives to the same patient population as recited in the method of Group III. Given that the method claims are directed to a method of treating at least three different patient populations; and given that the method claims are directed to the administration of two different compositions to at least three different patient populations for at least three different neuropathies, there is no special technical feature which links the claims, so unity of the invention is lacking.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
February 17, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655